K101044

510(k) SUMMARY

JUN 10 2010

Submitter:	Parkell, Inc. 300 Executive Drive Edgewood, NY 11717 TEL: 631-249-1134 FAX: 631-249-1242
Contact:	Daniel R. Schechter, Esq. General Counsel Parkell, Inc. 300 Executive Drive Edgewood, NY 11717
Submission Date:	13 APRIL 2010
Trade Name:	RETRIEVE
Common Name:	Dental Cement
Classification Name:	Dental Cement
Classification Product Code:	EMA
Predicate Devices:	PREMIER IMPLANT CEMENT (K033309), IMPROV TEMPORARY CEMENT (K982400), TEMPORARY RESIN CEMENT (K031212)
Device Description:	RETRIEVE is an acrylate- and methacrylate-based resin cement for semi-permanent cementation of porcelain, ceramic, resin and metal-based dental prostheses to dental implants. The cement is not considered fully "permanent," and is therefore substantially equivalent to temporary cements, because its bond strength is high enough to maintain the prosthesis in place during normal wear, but low enough to allow for removal by a dental professional for maintenance, replacement, and/or hygienic cleaning.
Intended Use:	RETRIEVE Implant Cement is a resin-based, self-curing, dual-component dental cement. It is intended for mid- to long-term (semi-permanent) cementation of porcelain, ceramic, resin, and metal-based dental prostheses to dental implants, while allowing retrieval of the prostheses, if necessary. RETRIEVE can also be used as a temporary filling material.
Tech. Characteristics:	RETRIEVE dental implant cement is a two-part cement and is typically supplied in a double-barrel, auto-mix syringe. The cement system does not require acid etching of tooth surfaces, and self-cures.

Substantial Equivalence: Parkell's RETRIEVE dental cement for implants has similar indications, principles of operation, and technological characteristics as the predicate devices. The minor differences in the device do not raise any new questions of safety or effectiveness. Thus, RETRIEVE is substantially equivalent to its predicate devices. A brief comparison to Premier Implant Cement, as an example, is as follows:

Property	RETRIEVE	Premier Implant Cement
Type of cement	Resin cement	Resin cement
Delivery System	Dual-barrel syringe	Dual-barrel syringe
Self-Cure	Yes	Yes
Working Time	2 minutes	2-2.5 min. gel phase
Setting Time	5 minutes	5 minutes
Average bond strength	5.5 MPa	4.7 MPa
Average bond strength of Titanium post to metal crown	2.7 MPa	1.7MPa
Average bond strength of Zirconia post to Zirconia crown	2.0 MPa	1.3 MPa

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Daniel R. Schechter
Vice President, Regulatory Affairs
Parkell, Incorporated
300 Executive Drive
Edgewood, New York 11717

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Re: K101044
Trade/Device Name: RETRIEVE Implant Cement
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: April 13, 2010
Received: April 14, 2010

Dear Mr. Schechter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101044

Indications for Use

510(k) Number (if known):

Device Name: RETRIEVE Implant Cement

Indications for Use:

RETRIEVE Implant Cement is a resin-based, self-curing, dual-component dental cement. It is intended for mid- to long-term (semi-permanent) cementation of porcelain, ceramic, resin, and metal-based dental prostheses to dental implants, while allowing retrieval of the prostheses, if necessary. Retrieve can also be used as a temporary filling material.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) AND/OR Over-The-Counter Use (21 CFR Part 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ken Mulay for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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